

510(K) SUMMARY

K970316

1. SUBMITTER:

Innovative Devices, Inc.
734 Forest Street
Marlboro, MA 01752
Telephone: 508-460-8229

APR 16 1997

Contact: Eric Bannon, V.P. of Quality Assurance and Regulatory Affairs

Date Prepared: April 14, 1997

2. DEVICE:

Innovative 8 mm Ligament Fastener
Classification Name: Single/multiple component bone fixation appliances
and accessories.
Trade Name: Innovative Devices Ligament Fastener

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Innovative Devices 8 mm Ligament Fastener was the Mitek 5 mm Ligament Anchor, marketed by Mitek Surgical, Norwood, MA.

4. DEVICE DESCRIPTIONS:

The Innovative 8mm Ligament Fastener is an implantable tendon fixation device complete with the instrumentation needed to effect ligament to bone repair. The devices consist of a high density polyethylene sleeve with an acetal drive pin which is deployed into a pre-drilled hole in the bone. The Fastener is deployed through the use of a hex driver, for screwing in the sleeve, and an inserter which drives the pin into the sleeve.

In addition to the Fastener, a stainless steel drill is available to establish the proper hole in the bone for the Fastener. All of the instrumentation except the Fastener will be offered as reusable devices and be autoclaved in the sterilization tray provided for this purpose.

The Fastener will be available as a sterile, single use device for use in both an open and arthroscopic procedures.

5. INTENDED USE:

The Innovasive Devices 8mm Ligament Fastener is intended for ligament to bone reattachment of Anterior and Posterior Cruciate Ligaments in patients with recurrent instability of the knee.

6. COMPARISON OF CHARACTERISTICS:

The Innovasive Devices 8mm Ligament Fastener is comprised of two polymer components; high density polyethylene and acetal plastic. This device is used to secure a ligament in a predrilled hole in bone. It remains fixed in the bone by the screw threads and also radial compression as the device is deployed.

The Mitek Ligament Anchor is comprised of titanium with nitinol arcs. The arcs are imbedded in the bone when placed in the predrilled hole. The intended use of the Mitek Ligament Anchor and the Innovasive Ligament Fastener are identical.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. Cadaver study: Comparison of the ultimate holding strength in the bone indicated, compared to the predicate device. The Innovasive Fastener holding strength was found to be equivalent to the strength of the predicate device at a .01 significance level.